

Amendments to the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) A capsule having a shell wall, a linker, or a capsule subunit, composed of a pharmaceutically acceptable composition comprising a copolymer of Ammonio methacrylate Copolymer Type A (Eudragit RL) or Ammonio methacrylate Copolymer Type B (Eudragit RS) ~~pharmaceutical composition comprising Eudragit RL 100 or RS 100~~ present in an amount of about 10 to about 80% w/w; at least one dissolution modifying excipient, present in a total amount of about 20% to about 70% w/w; a lubricant present in an amount of about 5% to about 25% w/w; and optionally a surfactant present in an amount of 0 to about 10%, a plasticizer present in an amount of 0 to about 10% w/w and/or a processing agent present in an amount of 0 to about 10% w/w.
2. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the copolymer is Ammonio methacrylate Copolymer Type A Eudragit is RL100.
3. (Currently amended) The shell wall, linker, or subunit composition according to Claim 2 wherein the copolymer Type A Eudragit is RL100 is present in an amount of about 15 to about 50% w/w.
4. (Currently amended) The shell wall, linker, or subunit composition according to Claim 2 wherein the copolymer Type A Eudragit is RL100 is present in an amount of about 20 to about 40% w/w.
5. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the surfactant is present in an amount of less than 2% w/w.
6. (Currently amended) The shell wall, linker, or subunit composition according to Claim 5 wherein the surfactant is sodium dodecyl sulphate or is a block copolymer of ethylene oxide and propylene oxide.
7. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the lubricant is stearyl alcohol, glycerol monostearate (GMS), talc, magnesium stearate, silicon dioxide, amorphous silicic acid, or fumed silica; and

combinations or mixtures thereof.

8. (Currently amended) The shell wall, linker, or subunit composition according to Claim 7 wherein the lubricant is present in an amount of about 10 to 30% w/w.

9. (Currently amended) The shell wall, linker, or subunit composition according to Claim 8 wherein the lubricant is stearyl alcohol.

10. (Currently amended) The shell wall, linker, or subunit composition according to Claim 9 wherein the stearyl alcohol is present from about 10 to about 15% w/w.

11. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the lubricant is stearyl alcohol.

12. (Currently amended) The shell wall, linker, or subunit composition according to Claim 11 wherein the stearyl alcohol is present from about 10 to about 15% w/w.

13. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the dissolution modifying excipient is a swellable solid.

14. (Currently amended) The shell wall, linker, or subunit composition according to Claim 13 wherein the swellable solid is a cellulosic derivatives of ethyl cellulose, cellulose acetate phthalate; hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxypropylmethyl cellulose phthalate, or other hydroxyalkylcellulose derivative, and combinations or mixtures thereof.

15. (Currently amended) The shell wall, linker, or subunit composition according to Claim 13 wherein the swellable solid is at least one of a hydroxypropyl cellulose, or hydroxypropylmethyl cellulose, and a combination or mixture thereof.

16. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the dissolution modifying excipient is composed of a blend of hydroxypropyl cellulose polymers, each having a differing molecular weight, present in a total amount of about 30% to about 80% w/w.

17. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the blend of hydroxypropyl cellulose polymers is ~~Klucel EF and Klucel JF, or Klucel EF, EJ and GF, or Klucel JF and GF~~ composed of polymers having a molecular weight averaged of 80,000 and 140,000 (Klucel EF and Klucel

JF), or 80,000, 140,000 and 370,000 (Klucel EF, JF and GF), or 140,000 and 370,000 (Klucel JF and GF).

18. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the dissolution modifying excipient is a non-reducing sugar, a low molecular solute, or a water soluble filler.

19. (Currently amended) The shell wall, linker, or subunit composition according to Claim 18 wherein the low molecular weight solutes or sugars are xylitol, mannitol, lactose, starch, or sodium chloride, or combinations or mixtures thereof.

20. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the dissolution modifying excipient is a disintegrant.

21. (Currently amended) The shell wall, linker, or subunit composition according to Claim 20 wherein the disintegrant is sodium starch glycollate, croscarmellose sodium, crospovidone (cross-linked polyvinyl pyrrolidone), copovidone, polyvinyl pyrrolidone; and combinations or mixtures thereof.

22. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the plasticizer is triethyl citrate (TEC), tributyl citrate, acetyl triethyl citrate (ATEC), acetyl tributyl citrate (ATBC), dibutyl phthalate, dibutyl sebacate (DBS), diethyl phthalate, vinyl pyrrolidone glycol triacetate, polyethylene glycol, polyoxyethylene sorbitan monolaurate, propylene glycol, or castor oil; and combinations or mixtures thereof.

23. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 wherein the processing agent is talc.

24. (Currently amended) The shell wall, linker, or subunit composition according to Claim 23 wherein the processing agent is present in an amount of about 1 to about 5 % w/w.

25. (Currently amended) The shell wall, linker, or subunit composition according to Claim 1 which further comprises an absorption enhancer.

26. (Currently amended) The shell wall, linker, or subunit composition according to Claim 25 wherein the absorption enhancer is chitosan, lecithin, lectin, a sucrose fatty acid ester, Vitamin E-TPGS; and combinations or mixtures thereof.

27. (Currently amended) A capsule having a shell wall, a linker, or other capsule subunit composed of a pharmaceutically acceptable pharmaceutical composition comprising a copolymer of Ammonio methacrylate Copolymer Type A (Eudragit RL) Eudragit RL100 present in an amount of about 15 to 50% w/w, a lubricant which is stearyl alcohol, and at least one dissolution modifying excipient which is a hydroxypropylcellulose derivative, wherein the shell wall, the linker or subunit all being comprised of the pharmaceutical composition.

28. (Original) The composition according to Claim 27 wherein the hydroxypropyl cellulose is a blend of hydroxypropyl cellulose's having differing molecular weight.

29. (Currently amended) The composition according to Claim 28 wherein the blend of hydroxypropyl cellulose is composed of polymers having a molecular weight averaged of 80,000 and 140,000 (Klucel EF and Klucel JF) Klucel EF and Klucel JF.

30. (Currently Amended) The composition according to Claim 1 ~~or 17~~ wherein the blend of hydroxypropyl cellulose is composed of polymers having a molecular weight averaged of 140,000 and 370,000 (Klucel JF and GF) Klucel JF and Klucel GF.

31. (Currently amended) The composition according to Claim 1 ~~or 17~~ wherein the blend of hydroxypropyl cellulose is composed of polymers having a molecular weight averaged of 80,000 and 370,000 (Klucel EF and Klucel GF) Klucel EF and Klucel GF.

32. (Currently amended) The composition according to ~~any one of Claims 28 to 32~~ claim 28 wherein the blend of hydroxypropyl cellulose is of equal % w/w.

33. (Currently amended) The composition according to ~~any one of Claims 28 to 32~~ claim 28 wherein the blend of hydroxypropyl cellulose is about 32% w/w.

34. (Currently amended) The composition according to Claim 27 wherein the hydroxypropyl cellulose HPC is present in an amount of about 50% w/w.

35. (Original) The composition according to Claim 27 which further comprises a wicking agent.

36. (Original) The composition according to Claim 35 wherein the wicking agent is

lactose.

37. (Original) The composition according to Claim 36 wherein the lactose is present in an amount of about 13% w/w.

38. (Cancelled)

39. (Currently amended) An injection molded capsule shell, linker or spacer having a composition as defined in ~~any one of Claims 1 to 38~~claim 1.

40. (Currently amended) A multicomponent injection molded capsule shell, linker or spacer having a composition as defined in ~~any one of Claims 1 to 38~~claim 1.

41. (Currently amended) A welded, or mechanically joined, multicomponent injection molded capsule shell, linker or spacer having a composition as defined in ~~any one of Claims 1 to 38~~claim 1.

42. (Currently amended) A multi-component pharmaceutical dosage form which comprises a plurality of sub-units, each sub-unit being selected from

a) a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment for release of the drug substance contained in the capsule compartment, and

b) a solid matrix, a capsule subunit, or linker being comprised of a pharmaceutical composition comprising a copolymer of Ammonio methacrylate Copolymer Type A or Ammonio methacrylate Copolymer Type B comprising Eudragit RL100 or RS100 present in an amount of about 15 to 80% w/w, at least one hydroxypropyl cellulose present in an amount of about 30% to about 70% w/w and containing a drug substance, the polymer being soluble, dispersible or disintegrable in a patient's gastro-intestinal environment for release of the drug substance ~~contained in the solid matrix~~, and in which, at least prior to administration to a patient, the sub-units are welded together or mechanically joined in an assembled dosage form.

43. (Original) A multi-component pharmaceutical dosage form according to Claim 42, in which the solid matrix also comprises a lubricant present in an amount of about 10 to about 25% w/w.

44. (Original) A dosage form according to Claim 42, in which at least one of the sub-units is a drug substance-containing capsule compartments having a wall with a thickness in the range of about 0.1 – 0.8 mm.

45. (Original) A dosage form according to Claim 42, in which at least one of the sub-units is a substantially immediate release sub-unit.

46. (new) A capsule having a shell wall, a linker, or a capsule subunit, comprising a pharmaceutically acceptable of:

#	Formulations	% w/w
1.	Ammonio methacrylate Copolymer Type A HPC of 370,000 mw (Klucel GF) Lactose Stearyl alcohol	25.00 50.00 13.00 12.00
2.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Lactose Stearyl alcohol	35.00 40.00 13.00 12.00
3.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Stearyl alcohol	25.00 63.00 12.00
4.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) HPC of 140,000 mw (Klucel JF) Stearyl alcohol	25.00 31.50 31.50 12.00
5.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Lactose Stearyl alcohol	25.00 50.00 13.00 12.00
6.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Stearyl alcohol Titanium dioxide	25.00 61.00 12.00 2.00
7.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Stearyl alcohol Succinic acid	24.00 50.00 12.00 13.00
8.	Ammonio methacrylate Copolymer	24.00

	Type A HPC of 80,000 mw (Klucel EF) Lactose Stearyl alcohol SDS	50.00 13.00 12.00 1.00
9.	Ammonio methacrylate Copolymer Type A Ammonio methacrylate Copolymer Type B HPC of 80,000 mw (Klucel EF) HPC of 140,000 mw (Klucel JF) Stearyl alcohol	21.60 2.40 32.00 32.00 12.00
10.	Ammonio methacrylate Copolymer Type A Ammonio methacrylate Copolymer Type B HPC of 80,000 mw (Klucel EF) HPC of 140,000 mw (Klucel JF) Stearyl alcohol	2.40 21.60 32.00 32.00 12.00

47. (new) A process for making a pharmaceutical dosage form comprising the steps of:

a) introducing a copolymer of Ammonio methacrylate Copolymer Type A (Eudragit RL) or Ammonio methacrylate Copolymer Type B (Eudragit RS) present in an amount of about 10 to about 80% w/w; at least one dissolution modifying excipient, present in a total amount of about 20% to about 70% w/w; a lubricant present in an amount of about 5% to about 25% w/w; and optionally a surfactant present in an amount of 0 to about 10%, a plasticizer present in an amount of 0 to about 10% w/w and/or a processing agent present in an amount of 0 to about 10% w/w; simultaneously, and at substantially the same location, into an elongated hot melt extruder;

b) mixing said copolymer and said excipient composition in the hot melt extruder to form a homogeneous composition therein and ejecting the homogeneous composition in the form of a strand from the hot melt extruder through a die at a location remote from said same location at which the copolymer and said excipient composition are introduced;

c) cutting the strand into pellets;

d) introducing said pellets into an injection molder and forming subunits of a thin-walled capsule compartment, a solid matrix subunit or a linker, from said pellets by injection molding.

48. (new) The process according to Claim 47, in which the hot melt extruder is maintained at a temperature not lower than the copolymer and said excipient composition melting points.

49. (new) The process according to Claim 49, in which the temperature in the hot melt extruder gradually increases along the length of the hot melt extruder, from said same location at which the copolymer and an excipient composition are introduced, to the die.

50. (new) The process according to Claim 49, in which the hot melt extruder comprises an elongated barrel having first and second opposite ends, and twin screws within the barrel for propelling copolymer and said excipient composition along the length of the interior of the barrel, said substantially same location at which the copolymer and said excipient composition are introduced is located adjacent the first end of the barrel, and said die is located adjacent the second end of the barrel.

51. (new) The process according to Claim 47 wherein the pharmaceutical dosage forms are assembled using said capsule compartments as components of said dosage forms.

52. (new) The process according to Claim 51 wherein the said capsule compartments of the assembled dosage form are connected together by at least one weld where adjacent parts of said components are in contact, or are mechanically joined in an assembled dosage form.